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|----------|------------------|-----|---------|-----|---------|----|
| Address: | COMMISSIONER     | ОF  | PATENTS | AND | TRADEMA | RK |
|          | Washington, D.C. | 202 | 31      |     |         |    |
|          | www.uspto.gov    |     |         |     |         |    |

| APPLICATION NO.                                  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |  |
|--|---------------|----------------------|-------------------------|------------------|--|--|
| 09/837,797                                       | 04/17/2001    | Henry C. Lin         | (18810-81652) 9913      |                  |  |  |
| ′ 759  | 90 09/16/2002 |                      |                         |                  |  |  |
| SIDLEY & AU                                      |               | EXAMINER             |                         |                  |  |  |
| 555 West Fifth Street Los Angeles, CA 90071-2909 |               |                      | SWARTZ, RODNEY P        |                  |  |  |
|  |               |                      | ART UNIT                | PAPER NUMBER     |  |  |
|  |               |                      | 1645                    |                  |  |  |
|  |               |                      | DATE MAILED: 09/16/2002 | 7                |  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del></del>   |   | Application N            | D                   | Applicant(s)                                 |              |  |  |
|---|---|--------------------------|---------------------|--|--------------|--|--|
| Office Action Summary   |   | 09/837,797               |                     | LIN ET AL.                                   |              |  |  |
|   |   | Examiner                 |                     | Art Unit                                     |              |  |  |
|   |   | Rodney P. Swa            | artz, Ph.D.         | 1645   |              |  |  |
|   | - The MAILING DATE of this communication app  | pears on the c v         | er sheet with the c | orresp ndence ad                             | ldress       |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                          |                     |  |              |  |  |
| Status<br>1)□   | Responsive to communication(s) filed on   |                          |                     |  |              |  |  |
| 2a)□  |   | — ·<br>nis action is non | -final              |  |              |  |  |
| 3)□   | Since this application is in condition for allowa   |                          |                     | osecution as to th                           | ne merits is |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |   |                          |                     |  |              |  |  |
| 4)⊠   | Claim(s) $\underline{1-45}$ is/are pending in the application   | ٦.                       |                     |  |              |  |  |
| 4   | 4a) Of the above claim(s) is/are withdra  | wn from conside          | eration.            |  |              |  |  |
| 5)□   | 5) Claim(s) is/are allowed.   |                          |                     |  |              |  |  |
| 6)□   | Claim(s) is/are rejected.   |                          |                     |  |              |  |  |
| 7)  | Claim(s) is/are objected to.  |                          |                     |  |              |  |  |
| •   | Claim(s) <u>1-45</u> are subject to restriction and/or  | election require         | ment.               |  |              |  |  |
| · · · _   | on Papers   |                          |                     |  |              |  |  |
| ,—  | The specification is objected to by the Examine   |                          |                     |  |              |  |  |
| 10)1  | The drawing(s) filed on is/are: a) ☐ acce   |                          | •                   |  |              |  |  |
| 44)[] 7   | Applicant may not request that any objection to the   | -                        |                     |  |              |  |  |
| י ו_ו   | he proposed drawing correction filed on   |                          |                     | ved by the Examin                            | er.          |  |  |
| If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.   |   |                          |                     |  |              |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                          |                     |  |              |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                          |                     |  |              |  |  |
| a) All b) Some * c) None of:  |   |                          |                     |  |              |  |  |
| 1. Certified copies of the priority documents have been received.   |   |                          |                     |  |              |  |  |
| Certified copies of the priority documents have been received in Application No   |   |                          |                     |  |              |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |                          |                     |  |              |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                          |                     |  |              |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |                          |                     |  |              |  |  |
| Attachment(s)   |   |                          |                     |  |              |  |  |
| 1) Notice   | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO-1449) Paper No(s) | 4)                       |                     | (PTO-413) Paper No<br>Patent Application (PT |              |  |  |

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**DETAILED ACTION** 

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to method of treatment of SIBO, classified in class 424,

subclass 9.1.

II. Claims 29-45, drawn to method of diagnosis of SIBO and kit, classified in

class 435, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct methods with different end results. Invention I

is a method of treatment of small intestinal bacterial overgrowth or condition caused by small

intestinal bacterial overgrowth. Invention II is a method and kits for diagnosis of small intestinal

bacterial overgrowth.

Because these inventions are distinct for the reasons given above, have acquired a

separate status in the art as shown by their different classification, and because while the searches

may overlap, the searches are not coextensive, restriction for examination purposes as indicated

is proper.

Applicant is advised that the reply to this requirement to be complete must include an

election of the invention to be examined even though the requirement be traversed (37

CFR 1.143).

**Election of Species** 

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2. This application contains claims directed to the following patentably distinct species of the claimed invention:

-- If applicant elects Invention I, the following species election is required:

**Species A** = nutrient deprivation

Species B = introduction of disinfectant composition

**Species** C = administration of mast cell membrane stabilizer

-- If applicant elects Invention II, the following species election is required:

**Species D** = detection of bile acid and/or folate

**Species** E = detection of sulfur-containing gas

**Species** F = detecting level of intestinal permeability

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the species to be examined even though the requirement be traversed (37 CFR 1.143).

- 3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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September 16, 2002

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11. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The

examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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January 8, 2003